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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/090,046	02/28/2002	Masanobu Munekata	81833.0035 6922		
26021	7590 06/06/2003				
HOGAN & HARTSON L.L.P. 500 S. GRAND AVENUE SUITE 1900 LOS ANGELES, CA 90071-2611			EXAMINER		
			SRIVASTAVA	SRIVASTAVA, KAILASH C	
			ART UNIT PAPER NUMBER		
			1651	1	
		•	DATE MAILED: 06/06/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary		Application N .	Applicant(s)			
		10/090,046	MUNEKATA ET AL.			
		Examin r	Art Unit			
		Dr. Kailash C. Srivastava	1651			
	- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address - Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status						
1)⊠	Responsive to communication(s) filed on Ma	arch 19,2003 as Paper Number 9 .				
2a)⊠	This action is FINAL . 2b) ☐ T	his action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims						
4)⊠ Claim(s) 8-12 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
	5) Claim(s) is/are allowed.					
· · · · ·	Claim(s) <u>8-12</u> is/are rejected.	•				
7)	Claim(s) is/are objected to.					
8)□	Claim(s) are subject to restriction and/	or election requirement.				
Application	on Papers					
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action. 12)☐ The oath or declaration is objected to by the Examiner.						
· · · · ·						
Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
 a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. 						
Attachment(s)						
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal F	r (PTO-413) Paper No(s) Patent Application (PTO-152)			

DETAILED ACTION

- 1. Applicants' amendment filed 03/19/2003 as Paper Number 9 in response to Office Action mailed November 19, 2003 as Paper Number 7 has been entered. The text of those sections of Title 35; U.S. Code not included in this action can be found in a prior office action.
- 2. Claims 8-12 are currently pending and are examined on merits.

Terminal Disclaimer

3. The terminal disclaimer filed on March 19, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,429,193 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 U.S.C. § 112

4. Claims 8-9 and 12 stand rejected under 35 U.S.C.§ 112, first paragraph for the reasons of record set forth at page 3 of the Office Action mailed November 19, 2002 as Paper Number 7.

Applicant's arguments regarding the rejection cited supra have been fully considered but are not persuasive. Citing reference to particular pages of their specification, Applicants argue that their invention is enabled for CCTF obtained from cementum and precementum from all mammalia, because even though the invention has been exemplified with bovine teeth, the specification at Page 7, line 7 to Page 11, line 2 discusses obtaining the claimed CCTF of invention from all mammalia and by exemplifying their invention with bovine tooth, applicants have satisfied the enablement requirement specified in MPEP. Applicants' invention as disclosed in cited sections of said specification is not enabled because as presented in the cited section, applicants' preference is bovine tooth (Page 8, Lines 16-17) and applicants claim a protein obtained from bovine tooth cementum/precementum. Said protein has specific molecular weight, amino acid composition and physical properties as well as the biological function of promoting the growth of gingival fibroblasts. Applicants, however, have not provided evidence or reasons why a molecule from other mammalia with this biological function would have the same specific suite of molecular weight, amino acid composition and physical properties? In absence of any other example of a protein obtained from cementum/preecementum from tooth of any other mammal, applicants' cited claim is

merely a prophetic assertion for obtaining said CCTF from any or all mammalia, and is therefore, enabled for a CCTF obtained from only bovine tooth cementum or precementum.

Claim Rejections - 35 U.S.C § 102

- 5. Claims 8-12 stand rejected under 35 U.S.C. § 102(b) as anticipated by Ogata et al. (Comp. Biochem. Physiol., Vol. 116B (3): 359-365, 1997) for the reasons of record set forth at pages 4-5 of the Office Action mailed November 19, 2002 as Paper Number 7.
- 6. All of applicant s' arguments regarding the Prior art reference have been fully considered but are not persuasive. Applicants argue that applicants' amended claim 8 patentably distinguishes applicants' invention from that of Ogata et al., and is not anticipated by Ogata et al. because applicants' CCTF has been extracted with saline. However, Ogata et al. disclose a preparation that despite background noise is comprised of a 67 kD material as shown in Figures 1 and 2B of Ogata et al. reference. Ogata et al. also clearly disclose that the highest chemotactic activity of human gingival fibroblasts (HGF) was observed with said preparation (See Figure 5 A, page 363). Thus, the material disclosed in Ogata et al., reference is comprised of the same chemotactic factor having all the properties of the CCTF as claimed in the instant application. It is noted that the Ogata et al. reference does not teach that their CCTF composition was obtained in the instantly claimed manner. However, the steps according to which a claimed composition is obtained do not patentably distinguish the composition, per se, in any shape or form. In order to be limiting, the claimed and referenced prior art compositions must structurally be different. In the instant case, the step according to which the claimed and referenced prior art composition is obtained does not create a limiting structural difference between the two compositions. When applicant claims a composition in terms of function and the composition of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C §§ 102 and 103, expressed as a 102/03 rejection (MPEP2112).

CONCLUSION

- 7. No claims are allowed.
- 8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).



A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expires later than six months from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Saving Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kallash C. Srivastava, Ph.D. Patent Examiner Art Unit <u>1651</u> (703) 605-1196

June 5, 2003

Jon P. Weber, Ph.D. Primary Examiner